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result in the development of products that are regulated by FDA.

[61 FR 39763, July 30, 1996, as amended at 70 FR 5558, Feb. 3, 2005; 70 FR 51568, Aug. 31, 2005]

§5501.102 Designation of HHS components as separate agencies.

- (a) Separate agency components of HHS. Pursuant to 5 CFR 2635.203(a), each of the twelve components of HHS listed below is designated as an agency separate from each of the other eleven listed components and, for employees of that component, as an agency distinct from the remainder of HHS. However, the components listed below are not deemed to be separate agencies for purposes of applying any provision of 5 CFR part 2635 or this part to employees of the remainder of HHS:
 - (1) Administration on Aging;
- (2) Administration for Children and Families:
- (3) Agency for Healthcare Research and Quality;
- (4) Agency for Toxic Substances and Disease Registry;
- (5) Centers for Disease Control and Prevention;
- (6) Centers for Medicare and Medicaid Services;
- (7) Food and Drug Administration;
- (8) Health Resources and Services Administration:
- (9) Indian Health Service;
- (10) National Institutes of Health;
- (11) Program Support Center; and
- (12) Substance Abuse and Mental Health Services Administration.
- (b) Definitions—(1) Employee of a component includes, in addition to employees actually within a component, an employee of the Office of the General Counsel whose regularly assigned duties and responsibilities principally involve the provision of legal services to the relevant component with respect to substantive programmatic issues.
- (2) Remainder of HHS means employees in the Office of the Secretary and Staff Divisions, employees of the Office of the General Counsel with Department-wide responsibility, and any HHS employee not in one of the 12 components designated as separate agencies in paragraph (a) of this section.
- (c) Applicability of separate agency designations. The designations in para-

- graph (a) of this section identify an employee's "agency" for purposes of:
- (1) Determining when a person is a prohibited source within the meaning of 5 CFR 2635.203(d) for purposes of applying:
- (i) The regulations at subpart B of 5 CFR part 2635 governing gifts from outside sources; and
- (ii) The regulations at §5501.106 requiring prior approval of outside employment and other outside activities; and
- (iii) The regulations at §5501.111 governing the receipt of awards by employees of the National Institutes of Health: and
- (2) Determining whether teaching, speaking or writing relates to the employee's official duties within the meaning of 5 CFR 2635.807(a)(2)(i).

[61 FR 39763, July 30, 1996, as amended at 70 FR 5558, Feb. 3, 2005; 70 FR 51568, Aug. 31, 2005]

§ 5501.103 Gifts from federally recognized Indian tribes or Alaska Native villages or regional or village corporations.

- (a) Tribal or Alaska Native gifts. In addition to the gifts which come within the exceptions set forth in 5 CFR 2635.204, and subject to all provisions of 5 CFR 2635.201 through 2635.205, an employee may accept unsolicited gifts of native artwork, crafts, or other items representative of traditional native culture from federally recognized Indian tribes or Alaska Native villages or regional or village corporations, provided that the aggregate market value of individual gifts received from any one tribe or village under the authority of this paragraph shall not exceed \$200 in a calendar year.
- (b) Limitations on use of exception. If the donor is a tribe or village that has interests that may be substantially affected by the performance or nonperformance of an employee's official duties, the employee may accept the gifts authorized by paragraph (a) of this section only where there is a written finding by the agency designee that acceptance of the gift is in the agency's interest and will not violate any of the